

Amendments to the Drawings:

The attached sheets of drawings include changes to Figures 1-5. These sheets, which include Figures 1-5, replace the original sheets including Figures 1-5.

Attachment: Replacement Sheets

REMARKS

Consideration of the present application in view of the above amendments and the following election is respectfully requested.

Claims 1-17, 19-28 and 31-51 were pending. Claims 12-17, 28 and 45 have been canceled without prejudice to future prosecution in a related application or acquiescing to the rejections in the Office Action. New claims 52-54 have been added. Accordingly, claims 1-11, 19-27, 31-44 and 46-54 are pending.

Support for new claims 52-54 may be found, for example, in the first full paragraph at page 5 of the clean version of the substitute specification submitted herein. No new matter has been added via the addition of the new claims.

Claims 1, 2, 4, 9, 10, 19-27, 31-34, 36-39, 43 and 46-50 have been amended. Such amendments have been made to enter minor changes without acquiescing to the rejections in the Office Action. Support for the amendments to claim 1 may be found, for example, in the examples of the present application. No new matter has been added via these claim amendments.

Objections to the Specification

The present specification stands objected to due to various informalities listed on pages 3 and 4 of the Office Action.

Applicant submits herein a substitute specification that corrects the informalities identified in the Office Action. In addition, Applicant has amended the Abstract as suggested in the Office Action. Applicant further submits that page 24 of the original English translation of the present application is blank, and the substitute specification submitted herein includes only 23 pages. Page 32 of the original English translation contains primarily the English translation of the description of Figures 1, 2, 4 and 5. Because such description has been incorporated in the replacement drawings, Applicant has deleted this page.

In view of the above remarks, Applicant submits that the objections to the specification have been overcome. Withdrawal of these rejections is respectfully requested.

Objection to the Drawings

Figures 1-5 stand objected to because the wording is in German.

Applicant submits herein replacement drawings in English. Accordingly, this objection has been overcome. Withdrawal of this objection is respectfully requested.

Sequence Identifier Requirement

The sequence listing of the present application stands objected to because Figure 1 contains sequences without sequence identifiers.

Applicant submits herein a corrected sequence listing that includes the three sequences (*i.e.*, SEQ ID NOs: 7-9) shown in Figure 1. Applicant has also amended the description of Figure 1 in the specification to refer to these new sequence identifiers. Accordingly, the objection to the sequence identifier requirement has been overcome. Withdrawal of this objection is respectfully requested.

Sequence Listing

The sequence listing text file submitted herewith includes no new matter that goes beyond the original application as filed. Applicant respectfully submits that the above-identified application is now in compliance with 37 C.F.R. §§ 1.821-1.825 and WIPO Standard 25.

Claim Objections

Claims 2, 4, 9, 19-28, 31, 33, 36, 37, 39, 43, 46, 47 and 50 stand objected to because of the informalities listed on pages 5-7 of the Office Action.

Applicant has amended claims 2, 4, 9, 19-27, 31, 33, 36, 39, 43, 46, 47 and 50 as suggested in the Office Action and canceled claim 28. Applicant submits in previously presented claim 37, the word “hybridization” was correctly spelled.

In view of the above remarks, Applicant submits that these objections have been overcome. Withdrawal of these objections is respectfully requested.

Rejections Under 35 U.S.C. 112, Second Paragraph

Claims 1-11 stand rejected under 35 U.S.C. 112, second paragraph, as indefinite. More specifically, it is asserted in the Office Action that because subpart (a) of claim 1 recites “amplifying a DNA segment using the nucleic acids from the biological sample as a template and a primer pair capable of amplifying a region of SEQ ID NO: 1 that encompasses position -215,” at least in one embodiment of this claim, amplification of an *M. tuberculosis* sequence segment may not include position -215 using such a primer pair.

To facilitate allowance and without acquiescing to the above rejection, Applicant has amended claim 1 to clarify that the amplified DNA segment comprises a region of SEQ ID NO: 1. Accordingly, Applicant submits that this ground of rejection under 35 U.S.C. 112, second paragraph, has been overcome. Withdrawal of this rejection is respectfully requested.

Claims 36-44 and 51 stand rejected under 35 U.S.C. 112, second paragraph, as incomplete for omitting essential steps. It is asserted in the Office Action that in claim 36 the step of differentially extracting microbial DNA from DNA that is not microbial in origin, but is from the host subject, is omitted.

Applicant respectfully traverses this ground of rejection. Applicant submits that the separation of the host DNA from the mycobacterial DNA is not essential. It is the nature of DNA amplification methods (e.g., PCR) that they are capable of amplifying a specific microbial sequence in the presence of a significant amount of unrelated DNA, such as host DNA. While DNA extracted from cultures such as disclosed in Example 1 of the present application does contain primarily mycobacterial DNA, it is not necessary for the extracted DNA to be free from host DNA. Thus, the method of claims 36-39 and 51 can be carried out without separation of *M. tuberculosis* DNA from host DNA.

In view of the above remarks, Applicant submits that this ground of rejection under 35 U.S.C. 112, second paragraph, has been overcome. Withdrawal of this rejection is respectfully requested.

Claim 24 stands rejected under 35 U.S.C. 112, second paragraph, as indefinite. More specifically, it is asserted in the Office Action that it is unclear if the first recitation of “the

other probe” in this claim consists of or comprises SEQ ID NO:5, and if the second recitation of “the other probe” in this claim consists of or comprises the complementary sequence of SEQ ID NO:5.

Applicant has amended claim 24 to clarify that the first recitation of “the other probe” comprises SEQ ID NO:5, and the second recitation of “the other probe” comprises the complementary sequence of SEQ ID NO:5. Accordingly, Applicant submits that this ground of rejection under 35 U.S.C. 112, second paragraph, has been overcome. Withdrawal of this rejection is respectfully requested.

Claim 25 stands rejected under 35 U.S.C. 112, second paragraph, as indefinite. More specifically, it is asserted in the Office Action that it is unclear if the first recitation of “the other probe” in this claim consists of or comprises SEQ ID NO:6, and if the second recitation of “the other probe” in this claim consists of or comprises the complementary sequence of SEQ ID NO:6.

Applicant has amended claim 25 to clarify that the first recitation of “the other probe” comprises SEQ ID NO:6, and the second recitation of “the other probe” comprises the complementary sequence of SEQ ID NO:6. Accordingly, Applicant submits that this ground of rejection under 35 U.S.C. 112, second paragraph, has been overcome. Withdrawal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. 102(b)

Claim 28 stands rejected under 35 U.S.C. 102(b) as anticipated by Fleischmann *et al.* (U.S. Patent No. 6,294,328).

To facilitate allowance, Applicant has canceled claim 28.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicant believes that the remaining claims of the present application are now allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,
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